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Docket No.: 28341/6114.N
(PATENT)

7/31/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lowery et al.

Application No.: 09/809,524 Group Art Unit: 1645

Filed: March 15, 2001 Examiner: A.M. Navarro

For: Salmonella Vaccine Materials and Methods

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the restriction requirement imposed by the Office Action mailed June 21, 2002, Applicant hereby elects the invention of Group I (claims 1-14), with traverse, for prosecution on the merits at this time. Applicant further elects, with traverse, the *ssaT* gene and SEQ ID NO:1.

Applicant requests that the restriction requirement be reconsidered because the Examiner has not shown that a serious burden would be required to examine all of the claims. M.P.E.P. § 803 provides:

> If the search and examination of an application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.)*

Thus, for a restriction to be proper, the Examiner must satisfy the following two criteria: (1) that independent and distinct inventions are being claimed (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. *See* M.P.E.P. § 803.

Applicant respectfully submits that the Examiner has not shown that these criteria have been satisfied. Specifically, the Examiner has not shown that it would be a serious burden to search and examine both of groups I and II together. A search relating to the methods of Group II would significantly overlap with the search required for the compositions of Group I, and the Examiner has not shown that an undue burden would be produced by the combined search.

Moreover, the support for restricting the pending claims is insufficient in that the product, or composition, has not been shown to be capable of use in two materially different processes. The Examiner identified the following two uses for the claimed *Salmonella* vaccine compositions: (1) an *in vivo* use to elicit an immune response (i.e., to elicit anti-*Salmonella* antibodies), and (2) an *in vitro* use to assay anti-sera. These two processes are not materially different. In the first-identified use, the *Salmonella* vaccine composition is used to generate the very antibodies that may be assayed in the second-identified use. In other words, the Examiner is distinguishing a process for generating antibodies and a process for testing the results to determine whether the antibodies were successfully generated. This is little more than viewing the same coin from two sides and does not establish the existence of two materially different processes for using the claimed vaccine compositions.

Beyond the preceding observations, Applicant submits that the Examiner's requirement that Applicant elect a particular *ssa* gene is inconsistent with current PTO practice based on the Commissioner's *sua sponte* decision to partially waive the requirements of 37 C.F.R. § 1.141 *et seq.* (see M.P.E.P. § 803.04). Those guidelines provide that up to 10 polynucleotides of unrelated sequence may be pursued in a single application. Moreover, the request to further elect a single disclosed sequence for the elected gene is inconsistent with M.P.E.P. § 803.04, which addresses the propriety of restricting polynucleotides encoding different polypeptides. The sequences disclosed in SEQ ID NO:1 and SEQ ID NO:2 of the instant application are the nucleotide sequences of the *ssaT* gene from *Salmonella dublin* and *Salmonella typhimurium*, respectively. The Examiner has not provided any support for the assertion that the same gene from two organisms would encode different proteins as that term is used in M.P.E.P. § 803.04. Accordingly, Applicant submits that the request to elect a single sequence of a single gene is improper.

For the foregoing reasons, reconsideration and modification or withdrawal of the restriction requirement is requested.

It is submitted that all claims are now in condition for allowance and Applicant respectfully requests an early notification thereof.

Dated: July 22, 2002

Respectfully submitted,

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TRANSMITTAL FOR RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Submitted herewith is a Response to Restriction Requirement. Applicants believe that no fee is due with this response. However, if it is determined that any appropriate fee is due, please charge Deposit Account No. 13-2855. A duplicate of this paper is enclosed.

Dated: July 22, 2002

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